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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,344	07/30/2003	Jorg J. Goronzy	07039-169002	9317

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/630,344

Applicant(s)

GORONZY ET AL.

Examiner

David A. Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Amendment of 7/30/03 has been entered. Claims 1-20 are pending. Claims 1-20 are under examination.

The disclosure is objected to because of the following informalities:

At page 1, applicant must enter Related Application Data pertaining to parent application 09/700,677 and earlier filed applications. The current status of applic. 09/700,677 must be provided. This data was partially provided on the Application Transmittal Sheet; however, there were no directions to enter this data into the specification.

Appropriate correction is required.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant was not in possession of a method which can determine a "predisposition of an individual to have a stable or unstable angina condition".

All of applicant's exemplifications of cytokine production patterns only involve studies among patients with UA, patients with SA, and normals/controls. No patient group studied is one that is "predisposed" to either UA or SA. Applicant has not shown whether the patterns of cytokine production are the cause of or the results of the conditions of UA and SA, and applicant has offered no theoretical model which would

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lead one to conclude, or even presume, that the patterns of cytokine expression would be altered from normal and would be any different between those patients “predisposed” to UA and those patients “predisposed” to SA.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As noted supra, applicant’s exemplifications of cytokine production patterns only involve studies among patients with UA, patients with SA, and normals/controls. No patient group studied is one that is “predisposed” to either UA or SA. Since applicant has not shown whether the patterns of cytokine production are the cause of or the results of the conditions of UA and SA, one could not reasonably predict that those patients “predisposed” to UA and those patients “predisposed” to SA would show any patterns of cytokine expression that would be altered from normal and that would be any different between these two groups of patients. Since one would have to conduct experimental studies in order to determine what these differential patterns of cytokine expression may be that would permit one to classify patients as “predisposed” to UA or “predisposed” to SA, the experimentation would be undue. Any study in which one is setting out to correlate diagnostic markers with a predisposal to any sort of or set of condition(s) involves undue experimentation, because one must 1) first select criteria, other than the variables to be studied, that will find those patients who might be “predisposed” and then 2) conduct a longitudinal study, that might require many years or decades, to determine

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which of those patients were, in fact “predisposed”. Since the results are unpredictable as to just which of many cytokines might serve as diagnostic markers of “predisposition” and since the experimentation required may be lengthy, the experimentation required before one could practice applicant’s method would be undue. Unless and until a process is refined and developed to the point where “specific benefit exists in currently available form” there is insufficient justification for granting a patent monopoly. See *Brenner v. Manson* 148 USPQ 689.

Prior to citing art, it is necessary to determine the effective filing date of the claims. Claims 1-20 are granted benefit of the 8/27/98 filing date of Prov. Applic. 60/098,120.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-19 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Liuzzo et al (J Am Coll Cardiol, 31, (2-Suppl. A), 187A).

The ref is cited because it has authors who are not inventors and because its publication date is not clear. In the absence of a publication date, it is presumed to pre-date the 8/27/98 filing date of Prov. Applic. 60/098,120 and is thus cited under 102(a).

Liuzzo et al teach the stimulation of PBMC with PMA and ionomycin. They teach detecting patterns of IL-2, IL-4 and IFN-gamma production by CD4+ and by CD8+ T-cells. They compare these patterns of expression among patients with UA, patients with SA and normals/controls in a table; such presentation in a table constitutes the “comparing” of step c) of claim 1.

Liuzzo et al conclude from these patterns of cytokine expression in this table that “SA was characterized by a high proportion of CD4+ cells producing IL-2 and IL-4. UA was associated with a high proportion of CD8+ cells producing IFN-gamma.” These conclusions constitute the “classifying” of step d) of claim 1; claim 1 is thus anticipated. To the extent that applicant may believe that the reference shows the opposite of the claim (i.e. that the ref shows how patients, who have been previously classified as to having a condition of UA or SA, display different patterns of cytokine production), claim 1 would have been obvious, since the reference shows an association between patterns of cytokine production and the classification of angina. To the extent that intellectual/mental steps, such as “comparing” and “classifying” carry no weight in overcoming prior art, the reference anticipates.

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Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liuzzo et al in view of Prussin et al.

The Liuzzo et al reference alone has been cited supra against claims 1-19. In the event that applicant deems the reference to not be enabling for the cell staining methods taught therein, Prussin et al is cited as a reference showing how one can simultaneously stain for CD and cytokine antigens and detect the staining by flow cytometry.

Claim 20 is rejected under 35 U.S.C. 102(a) as being anticipated by Liuzzo et al.

Liuzzo et al has been cited supra against claim 1. Liuzzo et al teach cytokine production patterns in patients who have UA and SA, rather than the patterns in patients “predisposed” thereto; however, it is noted that nothing in instant claim 20 requires that the cells of step a) be from a patient of any particular kind. To the extent that intellectual/mental steps, such as “comparing” and “classifying” carry no weight in overcoming prior art, the reference anticipates.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liuzzo et al in view of Prussin et al.

The Liuzzo et al reference alone has been cited supra against claim 20. In the event that applicant deems the reference to not be enabling for the cell staining methods taught therein, Prussin et al is cited as a reference showing how one can simultaneously stain for CD and cytokine antigens and detect the staining by flow cytometry.

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Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Prussin et al.

Prussin et al show how one can stimulate PBMC with PMA and ionomycin and then simultaneously stain for CD and cytokine antigens and detect the staining by flow cytometry. They simultaneously stain for CD4 and IFN-gamma as in instant claim 8. They simultaneously stain for CD8 and INF-gamma as in claim 9. They simultaneously stain for CD4 and IL-2 as, in claim 10. They simultaneously stain for CD4 and IL-4 as in claim 11. It is noted that Prussin et al employ PBMC from normal donors, rather than from patients with UA or SA or from patients predisposed thereto; however, it is noted that nothing in instant claims 1 and 20 requires that the cells of step a) be from a patient having or being predisposed to having any recited condition. To the extent that intellectual/mental steps, such as "comparing" and "classifying" carry no weight in overcoming prior art, the reference anticipates claims 1-11 and 20. Since claims 12-19 merely refer to comparing against a "reference frequency" these claims likewise are not distinguished from the prior art, except for a mental step.

On attached form PTO-1449 the examiner has lined out the Liuzzo et al (1998) and the Prussin et al references. These have been cited on attached form PTO-892, so that there will be images of these in the file record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 4/24/05 DAS

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182-1644